# COMMISSION IMPLEMENTING REGULATION (EU) 2015/2105

## of 20 November 2015

## approving the active substance flumetralin, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [1], and in particular Article 24 in conjunction with Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, Hungary received on 3 April 2012 an application from Exponent International Ltd on behalf of Syngenta Crop Protection AG for the approval of the active substance flumetralin. In accordance with Article 9(3) of that Regulation, Hungary, as rapporteur Member State, notified the Commission on 28 September 2012 of the admissibility of the application.

(2) On 30 October 2013 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the European Food Safety Authority (hereinafter 'the Authority') assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(3) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report in September 2014.

(4) On 20 November 2014 the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance flumetralin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 [2]. The Authority made its conclusion available to the public.

(5) The applicant was given the possibility to submit comments on the review report.

(6) On 29 May 2015, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for flumetralin and a draft Regulation providing that flumetralin is approved.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied.

(8) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(9) The Commission however considers that flumetralin is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Flumetralin is a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in fresh water is greater than 40 days and the long-term no-observed effect concentration for freshwater organisms is less than 0,01 mg/L. Flumetralin therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

[1] OJ L 309, 24.11.2009, p. 1.
[2] EFSA Journal 2014;12(10):3816. Available online: www.efsa.europa.eu

(10) It is therefore appropriate to approve flumetralin as a candidate for substitution.

(11) In accordance with Article 24(2) of Regulation (EC) No 1107/2009, candidates for substitution are to be listed separately in the Regulation referred to in Article 13(4) of Regulation (EC) No 1107/2009. It is therefore appropriate to add a Part E in the Annex to Commission Implementing Regulation (EU) No 540/2011 [1]. That Regulation should therefore be amended accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Approval of the active substance as a candidate for substitution**

The active substance flumetralin is approved as set out in Annex I as a candidate for substitution.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

1. In Article 1 of Implementing Regulation (EU) No 540/2011 the second paragraph is replaced by the following paragraph:

'The active substances approved under Regulation (EC) No 1107/2009 are as set out in Part B of the Annex to this Regulation. The basic substances approved under Regulation (EC) No 1107/2009 are as set out in Part C of the Annex to this Regulation. The low-risk active substances approved under Regulation (EC) No 1107/2009 are as set out in Part D of the Annex to this Regulation. The candidates for substitution approved under Regulation (EC) No 1107/2009 are as set out in Part E of the Annex to this Regulation.'

2. The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 November 2015.

*For the Commission*
*The President*
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

*ANNEX I*

| Common Name, Identification Numbers | IUPAC Name | Purity [1] | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|
| Flumetralin<br>CAS No 62924-70-3<br>CIPAC No 971 | *N*-(2-chloro-6-fluorobenzyl)-*N*-ethyl-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine | 980 g/kg<br>The impurity Nitrosamine (calculated as nitroso-dimethylamine) shall not exceed 0,001 g/kg in the technical material. | 11 December 2015 | 11 December 2022 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flumetralin, and in particular Appendices I and II thereof, shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to:<br>(a) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;<br>(b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;<br>(c) the risk to herbivorous mammals;<br>(d) the risk to aquatic organisms.<br>Conditions of use shall include risk mitigation measures, where appropriate.<br>The applicant shall submit confirmatory information as regards:<br>1. the technical specification of the active substance as manufactured (based on commercial scale production);<br>2. the compliance of the toxicity batches with the confirmed technical specification.<br>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 11 June 2016. |

[1] Further details on identity and specification of active substance are provided in the review report.

*ANNEX II*

In the Annex to Implementing Regulation (EU) No 540/2011 the following Part E is added:

'PART E

**Candidates for substitution**

| | Common Name, Identification Numbers | IUPAC Name | Purity [1] | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|---|
| 1 | Flumetralin<br>CAS No 62924-70-3<br>CIPAC No 971 | *N*-(2-chloro-6-fluorobenzyl)-*N*-ethyl-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine | 980 g/kg<br>The impurity Nitrosamine (calculated as nitroso-dimethylamine) shall not exceed 0,001 g/kg in the technical material. | 11 December 2015 | 11 December 2022 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flumetralin, and in particular Appendices I and II thereof, shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to:<br>(a) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;<br>(b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;<br>(c) the risk to herbivorous mammals;<br>(d) the risk to aquatic organisms.<br>Conditions of use shall include risk mitigation measures, where appropriate.<br>The applicant shall submit confirmatory information as regards:<br>1. the technical specification of the active substance as manufactured (based on commercial scale production);<br>2. the compliance of the toxicity batches with the confirmed technical specification.<br>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 11 June 2016. |

[1] Further details on identity and specification of active substance are provided in the review report.'